



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,719	10/20/99	MIYASHITA	M 10059-308(P2)

000570 HM22/0731
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EXAMINER
PADMANABHAN, K

ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/420,719	MIYASHITA ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 19, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Prosecution Application

1. The request filed on June 19, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/420,719 is acceptable and a CPA has been established. An action on the CPA follows.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The recitation of the control means being separate from the biosensor in claims 11 and 18 is vague and indefinite. It is unclear if this merely requires that the control means and sensing region are not adjacent one another, but are separated by an intermediate layer. Alternatively, does this recitation require that the sample treating instrument and biosensor are completely different devices that are not coupled in any manner? Furthermore, does "separate" refer to a physical or chemical separation?

6. Claim 12 recites the limitation "the measurement results". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 11, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bockowski (US Pat. 5,271,819). Bockowski discloses a sensor electrode and a method for detecting selected characteristics in a sample solution. The reference discloses the use of absorbents, such as activated carbon, to remove specific contaminants or interferants from the sample solution (col. 3). The solution is then allowed to reach the biosensor. The apparatus of the reference includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are also located on either sides of the control means, as a sample enters on one side of the adsorbent, travels through the adsorbent where interferants are removed, and then is released to the sample region on the other side of the adsorbent.
9. Claims 11-12, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al. (US Pat. 5,378,635). Yasuda et al. disclose a method of measuring catecholamine. The reference discloses sample pretreatment means and sample dispensing means in the form of a syringe, which is couple to the pretreatment means. A syringe inherently has sample introduction and sample releasing parts. Maleimide, mixed with a buffer solution to adjust the pH to around 7.3, is added to the sample dispensing means or the sample pretreatment means and reacts with SH compounds, which inhibits the interference of fluorescence inducing reaction.
10. Claims 11-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosman et al. (US Pat. 5,079,170). Rosman et al. disclose a sample applicator for use in immunoassays.

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The applicator comprises a tube with a filter matrix at an end thereof. Sample is filtered to remove interferants as it enters the tube, and is again filtered as it is discharged from the tube in the opposite flow direction. The applicator may also comprise a reagent disposed within the permeable filter matrix, wherein the reagent may include buffering salts or enzymes.

11. Claims 11-12, 14, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al. (US Pat. 4,270,923). Kondo et al. disclose a kit for the pretreatment of the body fluids comprising a tube packed with a carboxylic acid-type cation exchange resin fiber and a pipe fitted with a rubber suction cap, to which the tube is to be connected at its lower end. Preferably, the subject fluid is filtered through the fibrous layer, wherein interfering components are removed. The sample is introduced to the tube, filtered to remove interferants, and released at the other end of the tube.

12. Claims 11-12, 14, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Khanna et al. (US Pat. 4,654,311). Khanna et al. disclose serum pretreatment wherein serum is passed through a column containing alkylated silica gel to remove assay interferants. The present invention allows separation of digoxin from endogenous proteins present in serum samples to which digoxin is bound. It is inherent that the column has a sample introduction and sample-releasing part, with the filter material disposed therebetween.

13. Claims 11, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (US Pat. 5,492,834). Liu et al. disclose the pretreatment of body fluids comprising contacting a sample with a size exclusion gel and obtaining an eluant free of the lower molecular weight analytes (interferants). The eluant can then be assayed for the analyte of interest.

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14. Claims 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Barden (US Pat. 4,279,618). Barden discloses a method and apparatus for determining the level of sulfuric acid in atmospheric air that also contains interferants. The method comprises the removal of interferants before the measurement of sulfuric acid content. The apparatus includes a sample introducing part, a control means for removing the interferants, and a sample releasing part, wherein sulfuric acid content is measured after the interferants have been removed from the sample and it is released to the rest of the apparatus. The apparatus also comprises heating means of the sample.

15. Claims 11-12 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Blatt et al. US Pat. 5,945,345). Blatt et al. disclose a device for removing interferants comprising a filter including a solid phase support and an active chemical component for binding the interferant. In one embodiment, a sample is introduced to a solid phase support where the interfering substance is immobilized, and the "clean" sample is released.

Response to Arguments

16. Applicant's arguments filed June 19, 2001 have been fully considered and are sufficient to overcome the 112 rejections and the 102 rejections over Heller et al. (US Pat. 5,262,305), and Foulds et al. (US Pat. 5,124,253). However, they are not persuasive to overcome the 102 rejection over Bockowski (US Pat. 5,271,819) and Barden (US Pat. 4,279,618).

17. With respect to the Bockowski reference, applicant's argument that the reference does not teach a biosensor separate from the control means is not convincing. Since "separate" as recited in claim 11 is vague, it is interpreted that the reference does indeed teach control means separate from the biosensor. Bockowski discloses an apparatus in which interferants are

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absorbed in a filter. The sample solution then travels through an outlet and reaches the sensor. The sensor and the adsorbent of the device are not adjacent to each other. This rejection would be overcome if the 112, 2nd paragraph were overcome.

18. With respect to the Barden reference, since intended use is not given patentable weight, claims 11 and 16 taken together only require sample introduction and releasing parts, a control means (function not given patentable weight), and a heater. The reference clearly has all these recited components. In addition, since the function of the control means is not given patentable weight, any component of the device of the reference can be considered the control means. As such, the sensing portion of the device is separate from the control means, as they are not adjacent to one another.

19. It is also noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). *In the instant case, if read in the broadest sense, independent claim 11 only requires a sample introducing part, a control means, and a sample releasing part. The use of terms such as "for" indicates intended use. Therefore, the functions of the control means and the sample releasing part would not be given patentable weight unless they were recited as positive limitations of the appropriate parts of the device instead of as their intended use. Applicant should use terminology such as "wherein the control means...". This suggestion applies to*

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claims 11, as alluded to above, 12 (function of catalyst), 14 (function of adsorbent), 16 (function of heater), and 18 (function of substance and elastic).

Conclusion

Claims 11-18 are rejected.

References: Brayton et al., Switchenko et al., Schneider et al., Rabi et al., and Khanna et al. are cited as art of interest for teaching various pretreatment methods and devices.

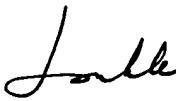
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

July 23, 2001


LONG V. LE
SUPERVISORY PATENT EXAMINER
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07/27/01